DOCKET NO.: ALZA-0377/ALZ5016USANP **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **J. Richard Gyory**	Confirmation No.: **7214**
Serial No.: **10/814,705**	Group Art Unit: **3767**
Filing Date: **March 30, 2004**	Examiner: **Andrew M. Gilbert**

For: **Electrotransport Device Having a Reservoir Housing Having a Flexible Conductive Element**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S BRIEF PURSUANT TO 37 C.F.R. § 41.37

This brief is being filed in support of appellant's appeal from the rejection of claims 17 to 22 dated January 8, 2009. A notice of appeal was filed on March 31, 2009.

1. REAL PARTY IN INTEREST

Based on information supplied and to the best of the undersigned's knowledge, the real party in interest in the above-identified patent application is the assignee, Alza Corporation of Palo Alto, California, a subsidiary of Johnson & Johnson, Inc. of New Brunswick, NJ.

2. RELATED APPEALS AND INTERFERENCES

The undersigned and the assignee know of no other appeals or interferences that will directly affect, be directly affected by, or have a bearing on, the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 17 to 22 are pending in the present application and stand rejected. Claims 17 to 22 are listed in Appendix A.

4. STATUS OF AMENDMENTS

The claims were last amended on November 18, 2008, and the amendments were entered.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed devices for the delivery of agents via electrotransport have a reservoir and a non-conductive housing for the reservoir that has a substantially flexible, electrically conductive element integrally molded within the housing. An electrode end of the electrically conductive element is positioned within the housing, a contact end is positioned outside of the housing, and a connecting portion is present between the two ends. The electrode end of the electrically conductive element is coated with an electrode coating, the contact end is coated with a contact coating, and the connecting portion is coated with a connecting coating that comprises a contact coating that may contain conductive particles. The electrically conductive element may be substantially planar.

The incorporation of a flexible electrically conductive element into the reservoir housing enables the drug reservoir and electrode, which are located inside of the reservoir housing, to be placed in electrical communication with a power source, which is located outside of the reservoir housing, without the need for forming an opening in the reservoir housing after it has been made.

The molding process used to form the reservoir housing is performed at high heat and pressure, and a substantially liquid and moisture impermeable bond is created between the material that forms the reservoir housing and the conductive element. The resulting reservoir housing is essentially a single integral component that does not require the fabrication of openings or other passages through the housing that would require subsequent sealing. By molding a conductive element into and through the reservoir housing during manufacture, problems associated with the leakage of water or moisture from inside the reservoir out into the electrical and mechanical components of the devices do not arise.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Three issues remain for resolution in this appeal:

1. Whether the Examiner has established that the subject matter of claims 17 to 22 is anticipated by, or would have been rendered obvious by, U.S. patent number 5,857,994 ("the Flower patent").

2. Whether the Examiner has established that the subject matter of claims 17 to 22 is anticipated by, or would have been rendered by, U.S. patent number 6,915,159 ("the Kuribayshi patent").

3. Whether the Examiner has established that claim 22 is indefinite due to insufficient antecedent basis in the claim for the phrase "the connection coating."

7. ARGUMENT

A. The Examiner has not established that the subject matter of claims 17 to 22 is anticipated by, or would have been rendered obvious by, the Flower patent.

As codified in 35 U.S.C. §§ 102(b) and 102(e), a patentable invention must be new:

> A person shall be entitled to a patent unless...(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or...(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent . . .

If every element as set forth in a claim is found, expressly or inherently, in a single prior art reference, then the claimed subject matter was not new and the claim is said to be "anticipated."[1]

To establish *prima facie* obviousness, the Patent Office must demonstrate that the cited prior art reference or combination of references teaches or suggests all the limitations of the claims.[2] Because obviousness is determined as of the time of invention, it is fundamental that the Patent Office must avoid the use of hindsight when assessing obviousness.[3] As the Supreme Court recently recognized, "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be

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[1] *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987).
[2] *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).
[3] See e.g., *KSR Int'l Co. v. Teleflex*, 127 S.Ct. 1727, (2007) (warning against "the distortion caused by hindsight bias . . . and arguments reliant on *ex post* reasoning.

combinations of what, in some sense, is already known."[4] To avoid the trap of hindsight, a finding of obviousness thus requires the Patent Office to identify "a *reason* that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does*."[5]

Independent claim 17 recites an electrotransport device comprising a reservoir and a non-conductive housing for the reservoir that comprises a substantially flexible electrically conductive element integrally molded within the non-conductive housing. The electrically conductive element comprises an electrode end positioned within the non-conductive housing and coated with an electrode coating; a connecting portion coated with a connecting coating comprising a flexible polymer; and a contact end positioned outside the non-conductive housing and coated with a contact coating. A substantially liquid and moisture-impermeable bond is created between the material forming the non-conductive housing and the conductive element.

Contrary to the Office's assertions, the Flower patent fails to suggest, much less describe, such electrotransport devices, and accordingly fails to anticipate the devices or render them obvious. For example, the Flower patent does not describe electrotransport devices in which an electrically conductive element is *integrally molded* within a reservoir housing and in which an electrode end of the conductive element is positioned *within* the housing and a contact end of the conductive element is positioned *outside* the housing. Instead, the Flower patent describes an iontophoretic drug delivery device that includes a controller 2 and a patch 4 containing active electrode 8 and return electrode 10.[6] The controller is electrically coupled to the patch using electronic interconnectors 26, which can be a printed flexible circuit, metal foils, wires, tabs, or electrically conductive adhesives.[7] Electronic interconnectors 26 do not correspond to the electrically conductive element of the claimed devices, however, and patch 4 does not correspond to the non-conductive housing of the claimed devices. As shown in figure 1 of the Flower patent, the electronic interconnectors 26 are not *integrally molded* within patch 4, electrode ends of the interconnectors 26 are not positioned *within* the patch, and contact ends of interconnectors 26 are not positioned *outside* the patch. As the Flower patent teaches, conductive pads 34 on extending narrow tab 32 are the portion of the device that *extend outside* of patch 4 to

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[4] *Id.*
[5] *Id.* (emphasis added).
[6] Figures 1 and 2 and col. 4, lines 15 to 30.
[7] Col. 4, lines 27 to 30.

electrically connect electrodes 8 and 10 to the controller 2. The patent explains that conductive pads 34 are "exposed," which those skilled in the art would readily understand to mean that a portion of each pad is on the *outside* of the patch, in contrast to the electrical connectors, which are not described as "exposed." In this regard, the patent teaches that "electrical connectors 26 may be one or more conductive paths extending from the electrodes 8 and 10 to exposed conductive pads 34."[8] Accordingly, the electrical connectors 26 are located *within* patch 4 and extend from electrodes 8 and 10 to the conductive pads 34, a portion of each of which is located outside of patch 4 to electrically connect electrodes 8 and 10 to controller 2.[9] Conductive pads 34, rather than the interconnectors, thus extend outside of patch 4 to connect electrodes 8 and 10 to controller 2, and the interconnectors 26 are therefore not integrally molded within patch 4 so that one end is positioned within the patch 4 and the other end positioned outside patch 4.

The Flower patent also does not describe electrotransport devices comprising an electrically conductive element in which an electrode end of the element is coated with an electrode coating, a contact end of the conductive element is coated with a contact coating, and a connecting portion of the conductive element is coated with a connection coating comprising a flexible polymer. In contrast to the Office's assertions, the Flower patent, in fact, lacks any teaching, description, or suggestion of coatings for any portion of interconnectors 26.

The Flower patent thus fails to describe or suggest every limitation recited in the pending claims, and, accordingly, fails to anticipate the claimed electrotransport devices. Moreover, those of ordinary skill in the art would have had no reason to design and produce electrotransport devices having the features recited in the claims before applicant's invention. Nothing in the Flower patent, when considered in view of the state of the art at the time of the invention, would have led those skilled in the art to fabricate electrotransport devices in which an electrically conductive element is integrally molded within a non-conductive housing such that one end of the element is positioned within the non-conductive housing and the other end is positioned outside the non-conductive housing. The claimed devices therefore would not have been obvious at the time of the invention in view of the description provided in the Flower patent, and the Examiner has failed to establish otherwise, and has thus failed to establish *prima facie* obviousness.

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[8] Col. 4, lines 63 to 65.
[9] Figure 4.

B. The Examiner has also not established that the subject matter of claims 17 to 22 is anticipated by, or would have been rendered obvious by, the Kuribayshi patent. Similar to the Flower patent, the Kuribayshi patent fails to describe or suggest all the limitations of the claims, and thus fails to anticipate, and render obvious, the claimed electrotransport delivery devices.

The Kuribayshi patent describes an electrode structure for iontophoresis devices in which a portion of an electrode layer (designated as 2 in Figures 1 and 2; Figures 4, 5, and 6 designate the anode electrode layer as 14 and the cathode electrode layer as 15) is located between an insulating layer 3 and a backing 1. As shown in Figure 3, portions of the electrode layer 2 make direct contact with a conductive layer 9 and with a cover member 8 where the insulating layer 3 is not present.[10]

The electrode layers of the devices described in the Kuribayshi patent (14 and 15 depicted in figure 6(c) and 2 in figure 1) do not correspond to the claimed electrically conductive element, and backing 1 does not correspond to the claimed non-conductive housing. Figures 1(c), 3, and 6(c) of the Kuribayshi patent clearly illustrate that electrode layers 14 and 15 are not integrally molded within a non-conductive housing. Moreover, a first end of electrode layers 14 and 15 is not located within a housing and a second end of electrode layers 14 and 15 is not located outside a housing. As seen in figures 3 and 6(c), electrode layers 14 and 15 are located between insulating layer 3 and backing 1, and portions of the electrode layers 14 and 15 make direct contact with conductive layer 9 and with cover member 8 where insulating layer 3 is not present. The entirety of electrode layers 14 and 15 is on the inner portion of backing 1. Accordingly, the electrode layers 14 and 15 are necessarily *not integrally molded* within a non-conductive housing, and, thus, a first portion of the electrode layer is not located within a housing and a second portion of the electrode layer is not located on the outside of a housing.

Moreover, the Kuribayshi patent also does not describe electrotransport devices comprising an electrically conductive element in which an electrode end of the element is coated with an electrode coating, a contact end of the conductive element is coated with a contact coating, and a connecting portion of the conductive element is coated with a connection coating comprising a flexible polymer. In contrast to the Office's assertions, the Kuribayshi patent, in fact, lacks any teaching, description, or suggestion of coatings for any portion of electrode layers 2, 14, and 15.

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[10] Figures 2, 3, and 6(c) and col. 5, lines 59 to 65.

The Kuribayshi patent thus fails to describe or suggest every limitation of the pending claims, and, therefore, fails to anticipate the claimed electrotransport devices. In addition, nothing in the Kuribayshi patent, when considered in view of the state of the art at the time of the invention, would have led those skilled in the art to produce electrotransport devices in which an electrically conductive element is integrally molded within a non-conductive housing such that one end of the element is positioned within the non-conductive housing and the other end is positioned outside the non-conductive housing. The claimed devices therefore would not have been obvious at the time of the invention in view of the description provided in the Kuribayshi patent, and the Examiner has failed to establish otherwise, and has thus failed to establish *prima facie* obviousness.

C. The Examiner has not established that claim 22 is indefinite. As stated in the M.P.E.P. at § 2173.05(e), "[o]bviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. *Energizer Holdings Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366 (Fed. Cir. 2006)(holding that 'anode gel' provided by implication the antecedent basis for 'zinc anode'); *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992)('controlled stream of fluid' provided reasonable antecedent basis for 'the controlled fluid.')"

Although the Examiner asserts that insufficient antecedent basis exists for the phrase "the connection coating" recited in claim 22, the claim depends from claim 17, which recites "a connecting portion coated with a connecting coating." Antecedent basis therefore exists in claim 17 for the phrase "the connection coating" recited in claim 22. The scope of claim 22 would thus be readily apparent to those skilled in the art, and the claim therefore meets the requirement of 35 U.S.C. § 112, second paragraph.

8. CLAIMS APPENDIX

17. An electrotransport device comprising:

a reservoir and a non-conductive housing for the reservoir that comprises a substantially flexible electrically conductive element integrally molded within the non-conductive housing,

the electrically conductive element comprising

an electrode end positioned within the non-conductive housing and coated with an electrode coating;

a connecting portion coated with a connecting coating comprising a flexible polymer; and

a contact end positioned outside the non-conductive housing and coated with a contact coating;

wherein a substantially liquid and moisture-impermeable bond is created between the material forming the non-conductive housing and the conductive element.

18. The electrotransport device of claim 17, wherein the non-conductive housing is a single integral component.

19. The electrotransport device of claim 18, wherein the electrotransport device is manufactured without the fabrication of openings or other passages through the non-conductive housing.

20. The electrotransport device of claim 17, wherein the conductive element comprises a substantially planar member.

21. The electrotransport device of claim 17, wherein the conductive element includes a base member having a conductive coating disposed thereon.

22. The electrotransport device of claim 17, wherein the connection coating contains conductive particles.

9. EVIDENCE APPENDIX

No evidence is being submitted with this appeal brief and no evidence that was entered by the Examiner is being relied upon in this appeal.

10. RELATED PROCEEDINGS APPENDIX

Since the undersigned and the assignee know of no other appeals or interferences that will directly affect, be directly affected by, or have a bearing on, the Board's decision in the pending appeal, no decisions rendered by a court or the Board in a related proceeding are being submitted herewith.

11. CONCLUSION

For the foregoing reasons, appellants request that the present patent application be remanded to the Examiner with an instruction to both withdraw the outstanding rejections, and to allow the appealed claims.

Respectfully submitted,

Date: June 1, 2009

/Jane E. Inglese/
Jane E. Inglese
Registration No. 48,444

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439